Articles

Avoiding Medication Mixups
Identifiable Imprint Codes

PRIYA VASUDEVAN, MB,BS; TERESA DEL GIANNI, PharmD, BCPS; *and*
WILLIAM O. ROBERTSON, MD, *Seattle, Washington*

This study was done to determine if current imprinting of solid medication forms permits health care professionals to identify the manufacturers involved so as to be able to activate the hierarchic identification system mandated by the Food and Drug Administration. We tested 15 representatives of 6 groups of health professionals for their ability to identify the manufacturer after having examined 30 solid-dosage forms drawn from a pseudo-random sample of stock hospital formulary products. The correct identification of the manufacturer was the sole criterion. Of the 2,700 opportunities, the manufacturer was able to be identified for only 43%. Nurses and medical students had a 35% success rate, pharmacists and poison center specialists a 55% success rate, and residents and attending physicians a 40% rate. None approached 95% accuracy. Currently employed imprints fail in their objective to permit health care professionals—or the general public—to rapidly identify prescription drugs. The manufacturers' logotypes need to be modified if this identification system is to be implemented. We propose a simple voluntary collaborative effort by the pharmaceutical industry to solve the problem.

(Vasudevan P, Del Gianni T, Robertson WO: Avoiding medication mixups—Identifiable imprint codes. West J Med 1996; 165:352–354)

Confronted by a burgeoning number of new pharmaceutical products in the late 1950s, the American Medical Association commissioned J. J. Hefferren, PhD, to develop a feasible mechanism for health care professionals to identify unknown tablets and capsules more rapidly and accurately. His solution involved constructing a ten-digit code for each solid-dosage medication form based on its unique physical characteristics.[1] Although theoretically sound, the resultant technique failed miserably in practice—consuming more than 15 minutes to reach an unacceptable 35% accuracy rate.[2] Variations on this theme proved no more effective. Unknown solid-dosage forms remained unknown until Eli Lilly Pharmaceutical Company developed and promulgated its "Identicode" system in 1967. This involved imprinting Lilly's name (logotype) plus a unique three-digit alphanumeric code on each of its solid-dosage products. When tested in practice, that technique achieved a 98% accuracy rate in less than 15 seconds—a dramatic improvement over all previous options.[3]

Over the decade of the 1970s, more than 90% of major prescription drug manufacturers adopted the imprinting technique—and over-the-counter drug manufacturers began to imprint their products as well. In 1980 the state of Washington was the first to adopt and implement legislation mandating the imprinting of all prescription solid-dosage forms—both trade name and generic products. Over the subsequent decade, more than 20 other states followed Washington's example so that virtually all such prescription medications were theoretically identifiable first by the manufacturer's name and then as to the individual product.

In 1991 the Washington legislature extended its mandate to apply to all nonprescription (over-the-counter) drugs as well. The legislature, however, agreed to postpone implementing that edict until after the Non-Prescription Drug Manufacturers Association had an opportunity to petition the Food and Drug Administration (FDA) to adopt a nationwide standard for imprinting of all solid-dosage forms so as to avoid having individual states mandate possibly conflicting imprinting requirements. After almost two years of discussion and debate on the matter, the FDA did adopt such a regulation in September 1993, choosing to retain the current "hierarchic" coding system. In general, this entails first identifying the manufacturer (or distributor) and then the manufacturer's unique product.[4]

The FDA's final regulations went into effect on September 19, 1995; all health care professionals, their patients, and the general public have access to precise

From the Washington Poison Center (Drs Vasudevan and Robertson), the Pharmacy Department, Children's Hospital and Medical Center (Dr Del Gianni), and the Department of Pediatrics (Dr Robertson), University of Washington School of Medicine, Seattle.

Reprint requests to William O. Robertson, MD, Medical Director, Washington Poison Center, 155 NE 100th St, Ste 400, Seattle, WA 98125-8012.

labeling information on each individual solid medication product. Such information has already proved effective in identifying "unknown medications" involved in accidental or purposeful overdoses, in avoiding dispensing errors, or in minimizing patient confusion between and among tablets or capsules after they have been taken home and removed from their original container to be stored in a pocket or purse.[5]

We postulate that the use of the technique might contribute to solving the widespread problem of "drug errors" in hospitals where, based on eight years of data from New York State, some 860 accidental deaths are projected to occur annually in our nation's hospitals.[6] For the technique to be effective, however, it first must enable users to identify accurately the manufacturer (or the distributor) from the name, logotype, symbol, or trademark imprinted on the tablet or capsule. To date, this step has presented problems.

In April 1992, Smolinski and Robertson published a report casting substantial doubt on the ability of even specially trained health professionals to achieve such identifications.[7] Attendees at the annual meeting of toxicologists could barely achieve an accuracy rate of 10% in deciphering admittedly selected logotypes. Unfortunately, no corrective actions followed. We decided to quantify the degree of accuracy able to be achieved by representatives of various groups of health care professionals when challenged to interpret the name of the manufacturer of a sample of 30 imprinted solid-dosage forms of common prescription drugs.

Methods

Two of us, an experienced pharmacist (T.D.G.) and a physician (P.V.), reviewed various solid-dosage forms on the formulary in a hospital approved by the Joint Commission on Accreditation of Healthcare Organizations, seeking a representative sample (n = 30) of the products with reference to their size, shape, color, and imprinting features. Five examples of each product—some trade name products and others generic products—were collected from single stock bottles (Figure 1). Each was placed in a separate plastic envelope and the entire sample was sequenced in a pseudo-randomized manner and subsequently attached to single white sheets of paper for inserting into three-ring binders. The physician proceeded to conduct all assessments to ensure uniformity of instructions, observations, and recordings. We had sought 15 volunteers from each of several readily accessible groups of health care professionals—pharmacists, poison information specialists, attending physicians, resident physicians, medical students, and registered nurses—hypothesizing that pharmacists and poison information specialists (all of whom were acquainted with and had actually used Micromedix Inc's computerized "Identidex" based on imprinting features) would be considerably more accurate than medical students or nurses in recognizing the manufacturers' names or symbols, with resident physicians and attending physicians falling somewhere in between the other two groups in their respective success rates. With careful attention to lighting in the room, decreasing possible distractions, and providing a hand-held magnifying glass, we allowed each volunteer as long as 15 seconds to examine each unknown medication so as to identify the specific manufacturer. Anything other than the correct answer was scored as an error.

Results

Virtually every individual health care professional approached agreed to participate; many volunteered the information that the study seemed long overdue because of specific problems they had already noted in attempting to identify unknown medicines. Thus, we rapidly secured 15 volunteers for each of the six groups: none took more than a total of ten minutes to complete the entire exercise, including the reading of specific directions before the experiment itself.

As seen in Table 1, the 30 manufacturers' names have

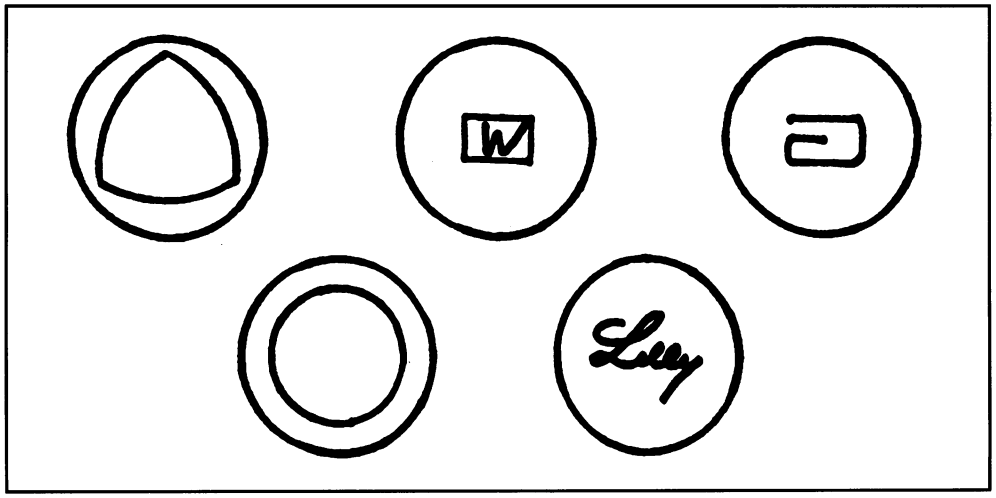

Figure 1.—Shown are 5 examples of logotypes from solid-dosage medication forms from which to identify the manufacturer.

TABLE 1.—*Descending Order of Correctly Identified Manufacturers (90 choices each)*

Name of Manufacturer	Identified Correctly, No. (%)	
Eli Lilly	90	(100)
Geigy Pharmaceutical	89	(99)
Glaxo Pharmaceutical	89	(99)
Wallace Laboratories	88	(98)
McNeil Pharmaceutical	88	(98)
Rugby	87	(97)
Roche Laboratories	86	(96)
DuPont Pharma	85	(94)
Biocraft Laboratories*	84	(93)
Adria Laboratories	76	(84)
Merck-Sharp-Dohme	50	(56)
A.H. Robins	42	(47)
Parke-Davis	41	(46)
Abbott Laboratories	37	(41)
Lederle Laboratories	31	(34)
Sandoz Pharmaceuticals	24	(27)
Danbury Pharmaceutical	16	(18)
Geneva Pharmaceutical	14	(16)
Sanofi Winthrop Pharmaceuticals	14	(16)
Sidmark Laboratories	5	(6)
Schering Corporation	4	(4)
Schiapparelli Searle	4	(4)
Roxane Laboratories	3	(3)
Purepac	2	(2)
Purdue Frederick Company	2	(2)
Biocraft Laboratories*	2	(2)
Johnson & Johnson Merck	0	(0)
Braintree Laboratories	0	(0)
Chase Laboratories	0	(0)
Winthrop Pharmaceuticals	0	(0)

*Manufacturer employed two different logotypes after corporate reorganization.

TABLE 2.—*Comparison of Accuracy Rates Among Health Professional Groups**

Group	Correct Choice, No. (%)	
Pharmacists	246	(55)
Poison center specialists	244	(54)
Physicians, attending	185	(41)†
Residents	168	(37)‡
Medical students	156	(35)
Nursing personnel	154	(34)
Totals	1,153	(43)

*Each group had 450 choices, for a total number of 2,700.
†The first 2 groups differed significantly from the third group, $P < .001$.
‡The fourth group differed significantly from the last 2 groups, $P < .05$.

been sequenced by the decreasing order of their recognizability from the imprint. For the first 7, 95% or more of the manufacturers' imprints were correctly identified; all had the name of the company spelled out on the capsule or tablet itself. In contrast, for the bottom 11, no such clarity of interpretation was to be found through the imprint symbol; of the 990 selection opportunities for those 11 products, only 20 (2.2%) were able to be accurately identified as to the specific manufacturer. Overall, among the sample of tablets and capsules selected for the study, two thirds presented problems to our subjects as they sought to identify the manufacturer involved. Hence, the step of interpreting the manufacturer's symbol or logotype presented a substantial barrier to precise identification of the specific products in question.

When the six participating groups were compared for their respective performances, there were some statistically significant differences between and among several of them as noted in Table 2. Such differences would seem of no practical importance because no group came close to achieving a "passing grade" (70%) or our sought-for accuracy rate of greater than 95%, which would seem a reasonable goal for any effective identification system.

Discussion

Although current technology is clearly able to make unit identification of unknown tablets and capsules virtually instantaneously available, its day-to-day use prohibits any meaningful reliance on this identification system. Whereas some pharmaceutical companies have chosen to optimize the potential of the identification system, others appear to have lagged considerably in achieving any such success. If a company's name is too lengthy to imprint, a derivative three-digit unique abbreviation of its name would certainly suffice—assuming that the Pharmaceutical Research and Manufacturers of America or a comparable group, the United States Pharmacopeial Convention, Incorporated, would serve voluntarily to develop a coordinated system for assigning "authorized abbreviations."

It is our premise that neither a health professional nor a member of the general public should have to rely on a specially trained third party to decipher imprints on solid-dosage forms. Were names or three-digit abbreviations to replace manufacturers' other logotypes or symbols, unit dose identification would immediately become feasible. Moreover, we are confident that were manufacturers to modify their tablet and capsule labeling by ensuring that the imprint was interpretable, they would improve their current image with the public. Thus, we strongly urge a voluntary effort to achieve this objective. Although conceivably bar coding or some other technology may eventually supersede imprinting, clear communication to consumers must remain the paramount objective to be achieved.

REFERENCES

1. Hefferren JJ: Identification guide for solid dosage forms. JAMA 1962; 182:1145–1302

2. Coldwell JG, Shoman AF Jr, Hurst CB Jr, et al: Identification of drugs—Use of the JAMA drug identification guide. JAMA 1964; 187:951–953

3. Symonds JK, Robertson WO: Drug identification: Use of coded imprint. JAMA 1967; 199:158–159

4. Bobbink S, Williams DH, Robertson WO: Use of drug imprints. Vet Hum Toxicol 1986; 28:160

5. Robertson WO: Imprinting solid medication forms: Status update. Vet Hum Toxicol 1995; 37:78–79

6. Robertson WO: Medication errors (Letter). Drug Safety 1994; 10:328–329

7. Smolinske SC, Robertson WO: Imprint coding on solid medication forms: Problems in interpretation. Vet Hum Toxicol 1992; 34:170–172